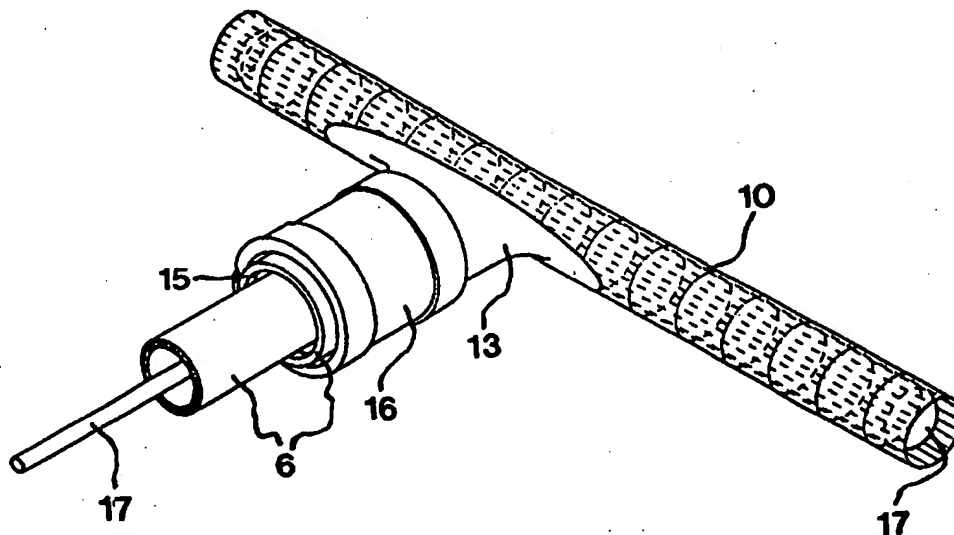




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61B 17/11	A1	(11) International Publication Number: WO 97/43961 (43) International Publication Date: 27 November 1997 (27.11.97)
(21) International Application Number: PCT/SE97/00804 (22) International Filing Date: 16 May 1997 (16.05.97) (30) Priority Data: 9601884-1 17 May 1996 (17.05.96) SE (71)(72) Applicant and Inventor: SOLEM, Jan, Otto (SE/SE); Nordmannavägen 20, S-237 31 Bjärred (SE). (74) Agent: AWAPATENT AB; P.O. Box 5117, S-200 71 Malmö (SE).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>With amended claims.</i>

(54) Title: A BY-PASS GRAFT**(57) Abstract**

A branching device for a blood vessel has a sleeve (10), which is radially extensible and has an opening (12) in its circumferential surface, and a collar (11) consisting of a fluid-tight material and fixed to the sleeve before the branching device is used. The collar has on the one hand a shoulder portion (13), which extends at least around the opening in the circumferential surface of the sleeve, and, on the other hand, a neck portion (14) integral with the shoulder portion and projecting radially from the opening in the circumferential surface of the sleeve.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

A BY-PASS GRAFT

The present invention relates generally to the field of vascular surgery and, more specifically, to a branching device for blood vessels, especially for bypass operations on the coronary vessels.

5 An increased flow resistance in the various coronary vessels can jeopardise the oxygen supply to the cardiac muscle. In some cases an expansion of vascular stenosis is possible. If the flow of blood in a vessel is completely or practically completely blocked, the only thing
10 to be done is to bypass the blocked portion to prevent an irreparable injury from arising. Such a bypass operation is usually effected by connecting a new vessel after the blocked point and connecting it to another blood vessel, for instance the aorta, which may give a sufficient flow
15 of blood to the blood vessel after the blocked point.

In practice, such a bypass operation requires the use of a heart-lung machine, i.e. that the heart be temporarily stopped since the bypass operation when connecting, for instance, the two vessels involved requires the
20 heart to be immovable. In consequence of the connecting technique employed and the use of the heart-lung machine, the operation will be relatively time-consuming and not completely without risk.

When larger vessels are involved, it is known from
25 e.g. US-A-5,456,712 to provide a branch by blocking the vessel by means of balloons on each side of the intended branch point, whereupon an incision is made in the blocked portion of the blood vessel. Then an expanded end of a vascular prosthesis is inserted through the incision and
30 a stent is inserted through the one blocking balloon to a position inside the incision, where finally the stent is expanded by means of a further balloon positioned inside the stent. For completely safe fixing of the expanded end to the area around the incision in the vessel, some sort
35 of suture is used, primarily for connecting the expanded

end of the vascular prosthesis with the blood vessel around the incision therein.

5 The prior-art technique implies that a blocking can be made on each side of the intended branch point, and that the stent can be inserted via the diseased vessel involved and through one of the blocking balloons. In practice, also a fixing of the expanded end of the vascular prosthesis relative to the vessel involved by means of some sort of suture is required.

10 The technique according to US-A-5,456,712 is thus not suited for use in thin vessels, such as the coronary vessels, or in other positions where the described blocking by means of a balloon from the inside of the vessel is not possible.

15 The object of the present invention is to provide a simple and reliable bypass of the coronary vessels without necessitating temporary internal blockings, preferably in a manner which can make it possible that the heart-lung machine need not be used, i.e. it should be possible to perform the bypass operation with the heart beating. Most preferably, it should be possible to carry out the operation by applying endoscopy.

20 According to the invention, this object is achieved by the branching device being given the features that appear from the accompanying claim 1.

25 The branching device thus has a sleeve, which is radially extensible and has an opening in its circumferential surface, and a collar which consists of a fluid-tight material and is fixed to the sleeve before the branching device is used and which has on the one hand a shoulder portion extending at least around the opening in the circumferential surface of the sleeve and, on the other hand, a neck portion integral with the shoulder portion and projecting radially from the opening in the circumferential surface of the sleeve.

30 The opening in the circumferential surface of the sleeve is preferably arranged unsymmetrically relative

to the ends of the sleeve. This confers an advantage since the necessary longitudinal incision in the blocked vessel need not be made longer than the distance from the neck portion to the nearest end of the sleeve, while the sleeve of the branching device can be retained safely in the vessel thanks to the sleeve obtaining a long part (seen from the neck portion), which must thus first be inserted into the opening in the vessel.

After the insertion of the sleeve into the vessel in a reciprocating movement, the short part of the sleeve is positioned completely beyond the opening in the vessel, while the long part of the sleeve covers the main part of the opening in the vessel and besides can extend beyond this a distance of essentially the same length as the short part of the sleeve. Once the sleeve is correctly positioned in the vessel, its position is to be fixed. This is possible according to the invention thanks to the sleeve being radially extensible and retaining its extended shape, i.e. the shape of the sleeve is permanently deformable. This results in an expansion of the vessel, which then clamps the sleeve in place and also clamps the shoulder portion of the collar against the sleeve.

The invention will now be described in more detail with reference to the accompanying drawings, in which

Fig. 1 is a perspective view and shows a heart with two schematically indicated bypasses of coronary vessels each having a blocking,

Fig. 2 is a perspective view and shows, among other things, a few parts included in one embodiment of a branching device according to the invention,

Fig. 3 shows some of the parts in Fig. 2 in an assembled state before insertion into a blocked vessel,

Fig. 4 shows the device after insertion into the blocked vessel, and

Fig. 5 shows the device after fixing in the blocked vessel.

The heart 1 shown in Fig. 1 has two coronary vessels 2, 3 each having a blocking 4, 5, i.e. a stenosis or an occlusion. Fig. 1 illustrates schematically how these blockings are bypassed by means of two vessels 6, 7 which can be taken from the patient himself. More specifically, one end of the vessel 6 is connected after the blocking 4, seen in the normal direction of flow in the vessel 2, and its other end is connected to the aorta 8, such that a sufficient quantity of oxygen-rich blood will be supplied to the already blocked coronary vessel 2 after the blocking 4 therein. The same applies to the vessel 3.

For effecting the connection of the vessel 6 to the coronary vessel 2, the embodiment shown in Figs 2-5 of a branching device according to the invention can be used. The main components of this branching device are a sleeve 10 and a collar 11 fixed thereto. The sleeve 10 preferably consists of metal, e.g. titanium, or some other material that is not rejected by the body tissue. Its construction is such as to be expandable or radially extensible, i.e. its diameter can be increased. Moreover, the sleeve 10 is permanently deformable and thus retains its shape after such an expansion.

A suitable material for the sleeve 10 is a net or some other material that permits said permanent deformation, i.e. an increase of the diameter of the sleeve 10, said increase normally being accompanied by a corresponding decrease of the length of the sleeve 10. A particularly suitable material is the so-called stent material, which is used in sleeves for expansion of constricted blood vessels.

According to the invention, the sleeve 10 further has an axially elongate opening 12, whose dimensions, when expanding the sleeve 10, will be distorted in a manner similar to the distortion of the actual sleeve 10, i.e. a shortening in the axial direction and an expansion in the circumferential direction. The opening 12 will thus obtain a decreased length in the axial direction of

the sleeve 10, but an increased width in the circumferential direction of the sleeve 10.

The collar 11 consists of a fluid-tight and preferably flexible or even elastic material, which of course must also be such as not to risk being rejected by the body tissue. More specifically, the collar 11 has a shoulder portion 13 and a neck portion 14.

The shoulder portion 13 has a shape substantially conforming to the shape of the sleeve 10. It has such a size as to overlap the opening 12 and thus extend over the sleeve 10 around the opening 12. The overlapping is also so great as to remain also in case of a certain change of the size of the opening 12, as will be described below. The shoulder portion 13 can also completely encompass at least part of or the entire sleeve 10, in which case the material of the shoulder portion 13 is so elastic as not to essentially counteract an expansion of the sleeve 10, as will be described below.

The neck portion 14 of the collar 11 is a direct extension of the shoulder portion 13 and essentially has the shape of a cylinder. The most important function of the neck portion 14 is to serve as connecting member for the new vessel 6.

For the connection between the neck portion 14 and the vessel 6, a rigid supporting sleeve 15 and a clamping or locking sleeve 16 can be used according to the embodiment illustrated in the drawings. The end of the vessel 6 is adapted to be inserted into and through the supporting sleeve 15, and the outermost part of the vessel 6 is then to be folded or pulled back over the outside of the supporting sleeve 15. This folding back of the end of the vessel 6 is shown in Fig. 2, but with the supporting sleeve 15 separated from the vessel 6. For completion of the connection, the supporting sleeve 15 with the pulled-on vessel 6 is inserted into the open end of the neck portion 14. Then the clamping sleeve 16 is arranged and clamped around the neck portion 14, which then together

with the interiorly situated, folded-back part of the vessel 6 is pressed against the outside of the supporting sleeve 15. As a result, a fixed and tight connection between the neck portion 14 and the vessel 6 is achieved.

5 The actual clamping sleeve 16 is advantageously divisible so as to be laterally movable over the neck portion 14 before the clamping operation, which suitably is effected by the clamping sleeve 16 having, at its ends that are free before clamping, hooks engaging each other
10 and permitting an easy tightening of the clamping sleeve 16 around the neck portion 14.

For fixing the sleeve 10 and the collar 11 relative to e.g. the blood vessel 2 in Fig. 1, use is made of a T-shaped balloon 17, the opening of which is situated
15 on that branch of the balloon which extends through the neck portion 14. By means of this balloon 17, the sleeve 10 can be expanded in its place within the blood vessel 2, such that the blood vessel expands and thus is pressed against the sleeve 10 for fixing the position thereof in
20 the blood vessel 2. At the same time the collar 11 will be squeezed between the blood vessel 2 and the sleeve 10, such that the position of the collar 11 will be safely fixed relative to the blood vessel 2 and a fluid-tight seal between this and the collar 11 is obtained without
25 necessitating any suture.

The balloon 17 can, as shown, be a single balloon, but alternatively it can be formed of two elongated balloons extending through the neck portion 14 and in different directions from the neck portion 14 through the
30 sleeve 10, so as to be inflatable via the neck portion 14 and, during inflation, expand the sleeve 10 in essentially the same fashion as in the case where the balloon 17 is a single balloon.

It is possible to first prepare the connection
35 between the collar 11 and the new vessel 6 with the balloon 17 situated inside the sleeve 10 and extending through the blood vessel 6 and out of the opposite end

thereof, as shown in Fig. 3. Subsequently, the sleeve 10 can in a reciprocating movement be inserted into, for instance, the vessel 2 through an opening 18 formed therein through a longitudinal incision, as shown in Fig. 4. Then
5 the branching device is fixed in the vessel 2 by inflating the balloon 17, whereby the sleeve 10 is expanded and shortened as shown in Fig. 5. Finally, the balloon 17 can be deflated and then be pulled out through the collar 11 and the vessel 6.

10 For completion of the operation, the free end of the new vessel 6 is to be connected to a blood vessel, for instance the aorta 8, which can give a sufficient flow of blood to the vessel 2 after the blocking 4.

An alternative method of carrying out a bypass operation by means of the branching device according to the
15 invention comprises the following steps.

Also in this case, the sleeve 10 is inserted in the vessel 2 through the opening 18 thereof, however without first connecting the vessel 6 with the collar 11. The
20 fixing of the sleeve 10 in relation to the blood vessel 2 is carried out by inflation of the balloon 17 also in this case, and then the balloon is removed by being opened and pulled out through the collar 11. Finally the new vessel 6, which has previously been connected to a blood
25 vessel, for instance the aorta 8, which can give a sufficient flow of blood to the vessel 2 after the blocking 4, and the neck portion 14 are connected by means of the supporting sleeve 15 and the clamping sleeve 16 in the same manner as described above.

30 It should be emphasised that in the two methods as described above, the collar 11 is even from the beginning fixed to the sleeve 10, and the balloon 17 is also even from the beginning inserted in the sleeve 10.

The expert realises that several modifications of
35 the above-described embodiment of a branching device are conceivable within the scope of the invention as defined in the appended claims.

CLAIMS

1. A branching device for a blood vessel, comprising
5 a sleeve (10), which is radially extensible and has an
opening (12) in its circumferential surface, c h a r -
a c t e r i s e d by a collar (11) which consists of a
fluid-tight material and is fixed to the sleeve before
10 the branching device is used and which has on the one
hand a shoulder portion (13) extending at least around
the opening in the circumferential surface of the sleeve
and, on the other hand, a neck portion (14) integral with
the shoulder portion and projecting radially from the
opening in the circumferential surface of the sleeve.
- 15 2. A branching device as claimed in claim 1,
c h a r a c t e r i s e d in that the opening (12) in the
circumferential portion of the sleeve (10) is unsymmetri-
cally positioned relative to the ends of the sleeve.
3. A branching device as claimed in claim 1 or 2,
20 c h a r a c t e r i s e d in that the sleeve (10) consists
of a net-like material.
4. A branching device as claimed in claim 3,
c h a r a c t e r i s e d in that the sleeve (10) consists
of a stent material.
- 25 5. A branching device as claimed in any one of
claims 1-4, c h a r a c t e r i s e d in that the shape
of the sleeve (10) is essentially permanently deformable
when increasing the diameter of the sleeve.
6. A branching device as claimed in any one of
30 claims 1-5, c h a r a c t e r i s e d in that the collar
(11) consists of an elastic material.
7. A branching device as claimed in any one of
claims 1-6, c h a r a c t e r i s e d in that the shoul-
der portion (13) of the collar (11) is attached to the
35 outside of the sleeve (10).
8. A branching device as claimed in any one of
claims 1-7, c h a r a c t e r i s e d by a balloon (17)

which is inserted in the sleeve (10) and is inflatable via the neck portion.

9. A branching device as claimed in claim 8, characterised in that the balloon (17) is
5 T-shaped.

10. A branching device as claimed in any one of claims 1-9, characterised in that the shoulder portion (13) fully encompasses at least part of the sleeve (10).

AMENDED CLAIMS

[received by the International Bureau on 15 October 1997 (15.10.97);
original claims 1 and 8-10 replaced by amended claims 1,8 and 9 (2 pages)]

1. A branching device for a blood vessel, comprising
5 a sleeve (10), which is radially extensible and has an
opening (12) in its circumferential surface, c h a r -
a c t e r i s e d by a collar (11) which consists of a
fluid-tight material and is fixed to the sleeve before
the branching device is used and which has on the one
10 hand a shoulder portion (13) extending at least around
the opening in the circumferential surface of the sleeve
and, on the other hand, a neck portion (14) integral with
the shoulder portion and projecting radially from the
opening in the circumferential surface of the sleeve; and
15 a balloon (17) inserted in the sleeve (10) and inflatable
via the neck portion.

2. A branching device as claimed in claim 1,
c h a r a c t e r i s e d in that the opening (12) in the
circumferential portion of the sleeve (10) is unsymmetri-
20 cally positioned relative to the ends of the sleeve.

3. A branching device as claimed in claim 1 or 2,
c h a r a c t e r i s e d in that the sleeve (10) consists
of a net-like material.

4. A branching device as claimed in claim 3,
25 c h a r a c t e r i s e d in that the sleeve (10) consists
of a stent material.

5. A branching device as claimed in any one of
claims 1-4, c h a r a c t e r i s e d in that the shape
of the sleeve (10) is essentially permanently deformable
30 when increasing the diameter of the sleeve.

6. A branching device as claimed in any one of
claims 1-5, c h a r a c t e r i s e d in that the collar
(11) consists of an elastic material.

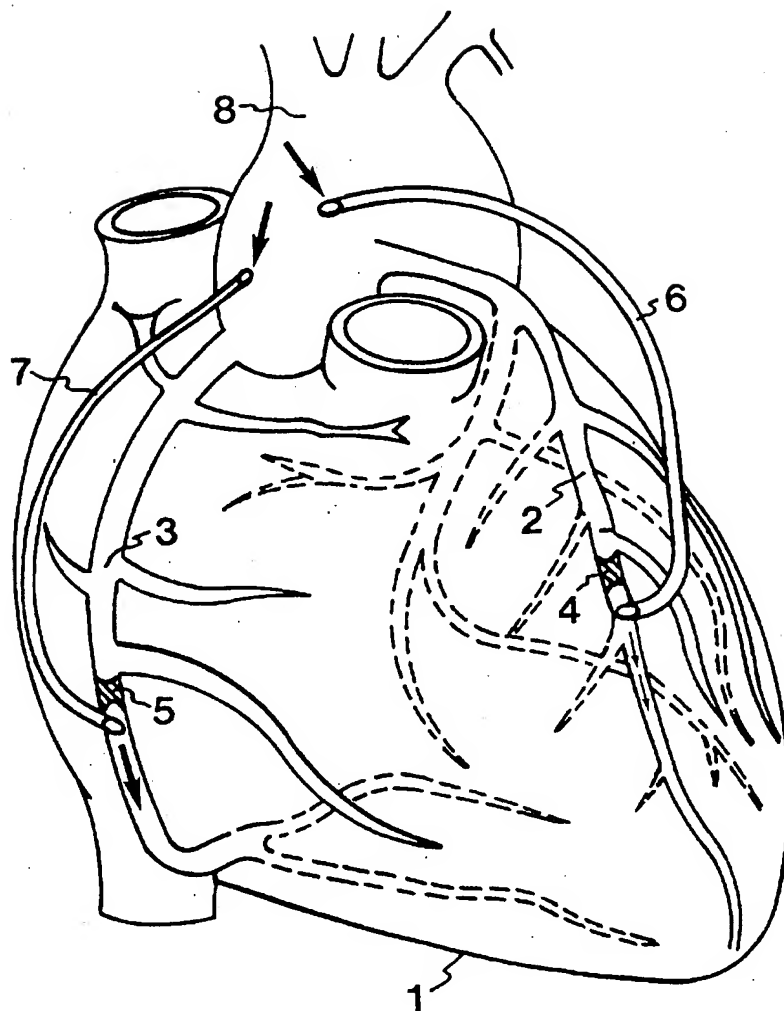
7. A branching device as claimed in any one of
35 claims 1-6, c h a r a c t e r i s e d in that the shoul-
der portion (13) of the collar (11) is attached to the
outside of the sleeve (10).

8. A branching device as claimed in any one of claims 1-7, characterised in that the balloon (17) is T-shaped.

5 9. A branching device as claimed in any one of claims 1-8, characterised in that the shoulder portion (13) fully encompasses at least part of the sleeve (10).

1/3

FIG.1



2/3

FIG.2

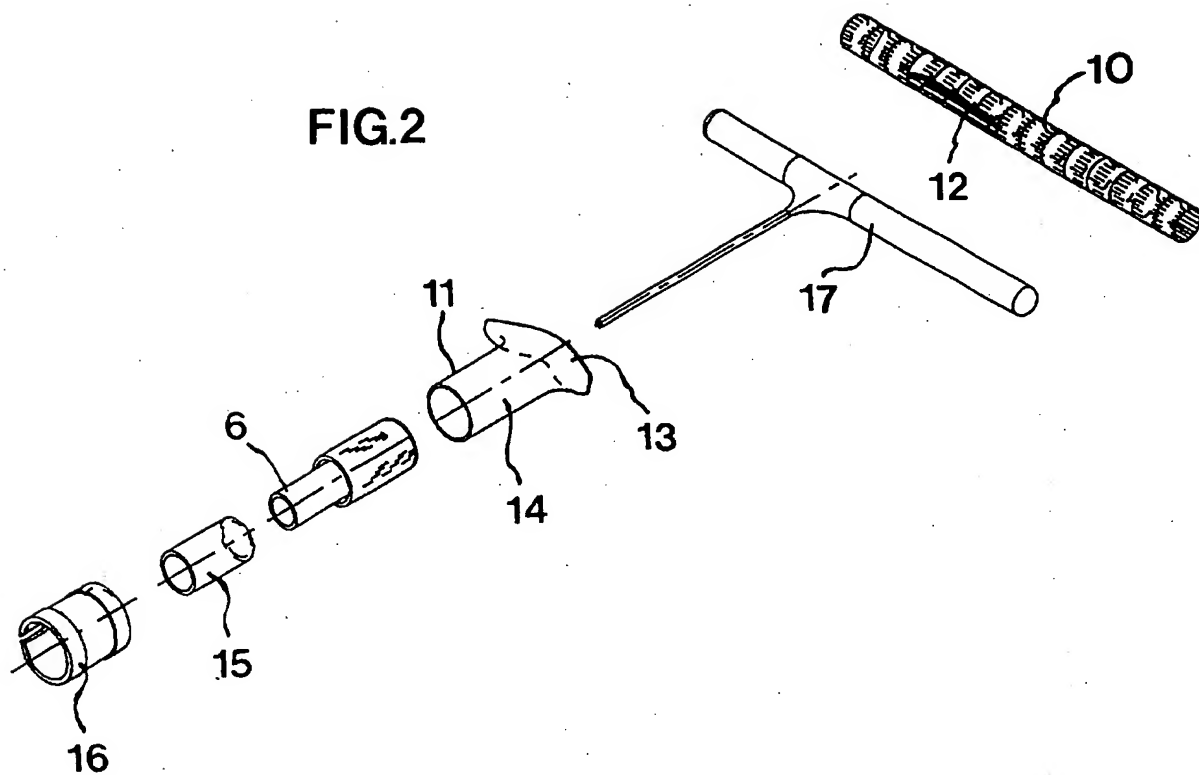
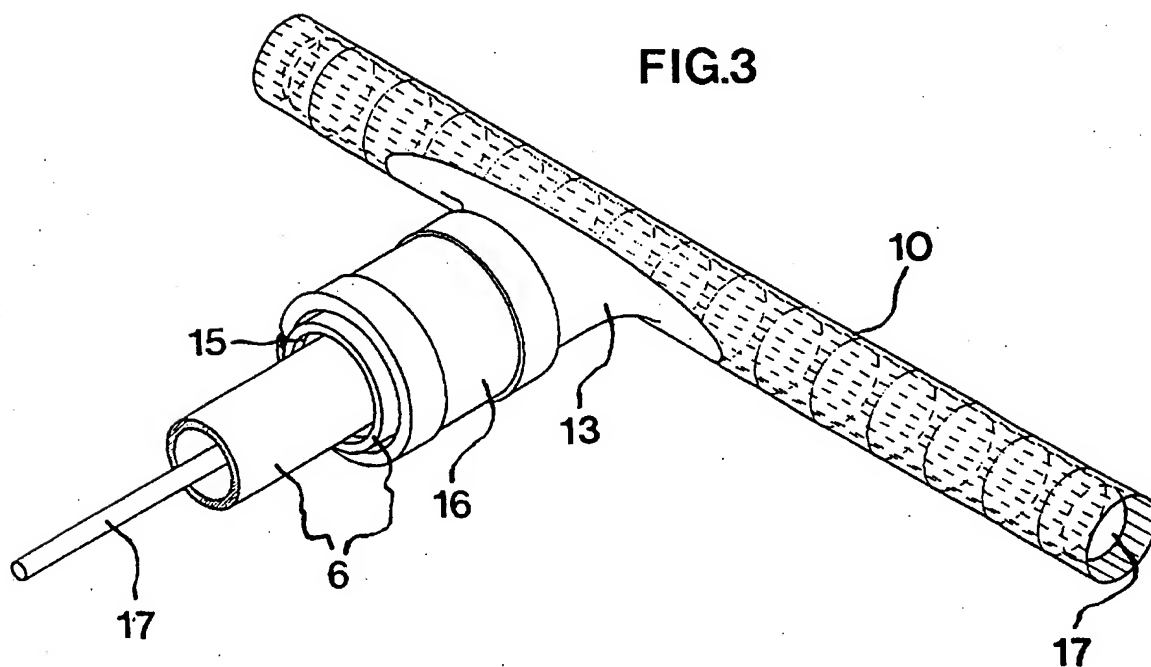


FIG.3



3/3

FIG.4

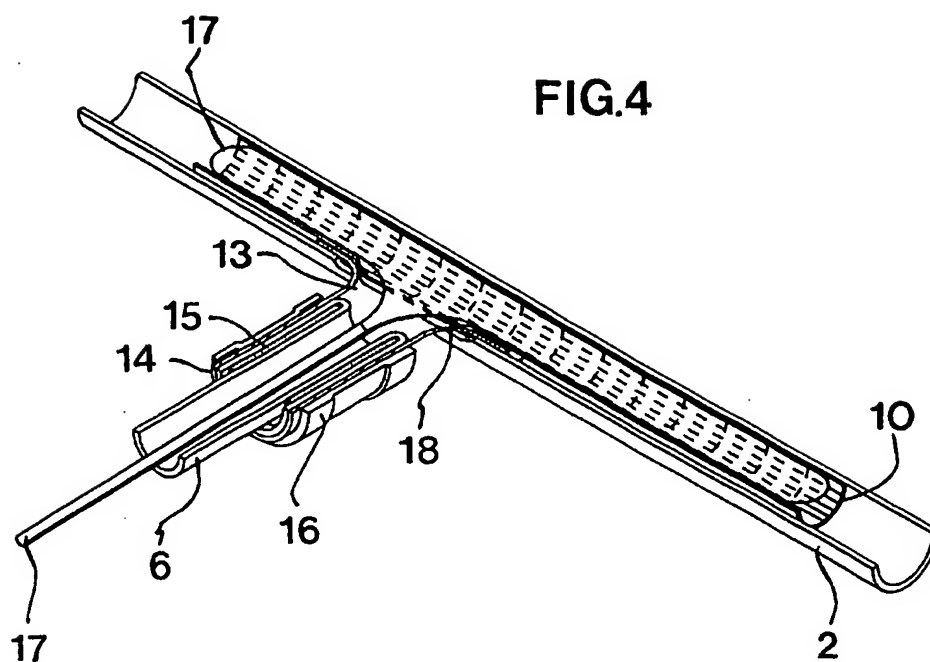
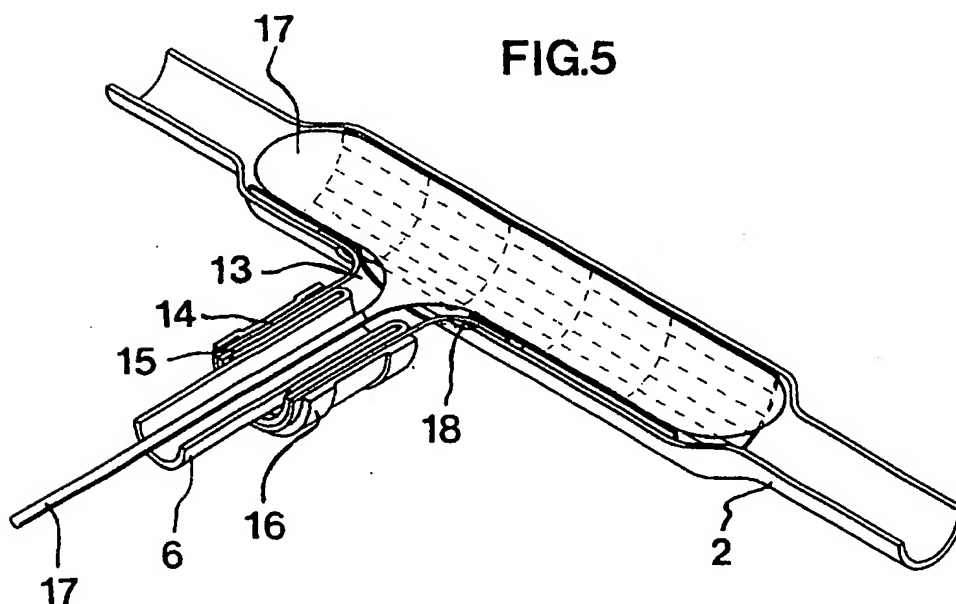


FIG.5



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/00804

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 8806865 A1 (BIEMANS, ROGIER, GUIDO, MARIE), 22 Sept 1988 (22.09.88), figure 5, page 5, last part --	1-10
X	US 5304220 A (THOMAS J. MAGINOT), 19 April 1994 (19.04.94), column 12, line 21 - line 32 --	1-10
A	US 5443497 A (ANTHONY VENBRUX), 22 August 1995 (22.08.95), see whole document --	1
X	US 5456712 A (THOMAS J. MAGINOT), 10 October 1995 (10.10.95), column 11, line 61 - line 65 --	1-10

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

12 August 1997

Date of mailing of the international search report

04 -09- 1997

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Anette Hall

Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/00804

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P	US 5571167 A (THOMAS J. MAGINOT), 5 November 1996 (05.11.96), column 11, line 66 - column 12, line 9 -- -----	1

INTERNATIONAL SEARCH REPORT

06/08/97

International application No.

PCT/SE 97/00804

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8806865 A1	22/09/88	AU 1571588 A NL 8700667 A	10/10/88 17/10/88
US 5304220 A	19/04/94	US 5456712 A US 5571167 A US 5211683 A	10/10/95 05/11/96 18/05/93
US 5443497 A	22/08/95	AU 1256095 A EP 0730436 A WO 9514442 A	13/06/95 11/09/96 01/06/95
US 5456712 A	10/10/95	US 5571167 A US 5304220 A US 5211683 A	05/11/96 19/04/94 18/05/93
US 5571167 A	05/11/96	US 5456712 A US 5304220 A US 5211683 A	10/10/95 19/04/94 18/05/93